REMARKS

I. Amendments

By this amendment, claims 1, 9-11 and 18-21 have been amended.

This amendment adds no new matter to the specification, but rather is only made to correct a minor typographical error.

No amendment of inventorship is necessitated by this amendment.

II. Discussion of the Rejection under 35 U.S.C. Sec. 103(a) over Lundberg

Claims 1, 2, 4-7 and 13-21 have been rejected under 35 U.S.C. Sec. 103(a) as allegedly obvious over Lundberg, U.S. Patent No. 6,132,770. Applicants respectfully traverse the rejection as the cited art is directed to a different dosage form having different requirements from the presently claimed preparations; and the cited art does not describe buccal disintegration time. Because of these differences, the cited art actually teaches away from the present invention as set forth in the pending claims, as will be discussed in the following paragraphs.

Different Dosage Form

The aspect of Applicants' invention as set forth in the pending independent claim 1 is directed to rapidly disintegrable solid preparations of specified composition having a certain range of buccal disintegration time. The goal of the invention (preparations as set forth in claim 1) is described succinctly on page 27, line 29- page 28, line 4 of the specification, where it is stated that "the present invention is advantageously used in (a) cases where administration without water is necessary, (b) cases of administration to a patients who have difficulty in swallowing tablets, or (c) cases of administration to the aged or children where there is a fear of blocking the throat if it is in usual tablet form. "

By contrast, the cited reference is directed to multiple unit effervescent tablets, as indicated by the title of the patent. The utilization of the effervescent tablets is described in col. 1, line 61 – col. 2, line 2 of the cited reference wherein it is stated that "[p]rior to being taken by the patient, an effervescent composition is dissolved and/or dispersed in for example an aqueous

medium, such as drinking water." The cited reference also states that "[e]ffervescent compositions usually contain, in addition to the active ingredient, a source of carbon dioxide (such as an alkaline carbonate or bicarbonate) and an acid (such as for instance citric acid)." in col. 2, lines 3-6.

No Measure of Buccal Disintegration Time

Should further clarification be required, Applicants wish to draw the Examiner's attention to the fact that the time measured in the examples of the cited reference was *not* a buccal disintegration time. It was an *effervescence* time. The Examiner is respectfully requested to compare the effervescence time test in the cited art (col. 18, lines 16-24 for example) to the buccal disintegration time test as described in the specification (page 27, lines 3-6 and page 30, line 29 – page 31, line 1). The buccal disintegration time recited in claim 1 is not disclosed by the cited reference.

Cited Art Teaches Away from the Present Invention

To be perfectly clear, the tablets of the '770 patent dissolve in a glass of water, not in a patients' mouth. Those skilled in the art understand this, and would not look to a reference directed to effervescent tablets for direction when contemplating creation of preparations for buccal dissolution. This is so because an effervescent tablet will be dissolved in a large amount of water, while a buccally disintegrable tablet will be dissolved in only a minimal amount of water (saliva).

The more water available to aid dissolution, the faster the dissolution will be. Conversely, in an environment wherein only a limited amount of water is available (as saliva in the mouth) it would be expected that dissolution would take longer. The cited art provides examples having an effervescence time of 55 seconds. Logically, the buccal dissolution time of the effervescent tablets in the cited art (were they to be buccally administered) would have to be longer than 55 seconds, due to decreased amount of water for dissolution. Therefore, the effervescing tablets effervescence time (cited by the Examiner as about 55 seconds) actually teaches away from the 5 –50 second buccal dissolution time claimed for the recited preparations.

Claims 2, 4-7 and 13-17 depend upon claim 1. Applicants submit that the more specific dependent claims are also unobvious for the reason provided above.

Independent claim 21 is directed to tablets, while independent claims 18-20 are directed to methods. In each of these claims, a specific range of buccal dissolution time is recited. As explained in the preceding paragraphs, the cited art does not teach or suggest such rapid buccal dissolution. Therefore, Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 103(a) rejection over Lundberg.

III. Conclusion

Reconsideration of the claims in view of the arguments made above is solicited. Should the Examiner believe that a conference with Applicants' attorney would advance prosecution of this application, she is respectfully requested to call Applicants' attorney.

Respectfully submitted,

Dated: April 21, 2004

Elaine M Ramesh

(847) 383-3391
(847) 383-3372

Elaine M. Ramesh, Ph.D., Reg. No. 43,032
Mark Chao, Ph.D., Reg. No. 37,293

Attorney for Applicants
Customer No. 23,115

Takeda Pharmaceuticals North America, Inc.
Intellectual Property Department
Suite 500, 475 Half Day Road
Lincolnshire, IL 60069 USA

Certificate of Mailing under 37 CFR 1.10

The undersigned hereby certifies that this document, along with any attachments, is being deposited in an envelope addressed to The Commissioner of Patents and Trademarks, with sufficient postage with the United States Postal Service EXPRESS MAIL Post Office to Addressee Service on this date April 21, 2004 .

Express Mail Label No. EV 410710575 US

Gail L. Winokur

Printed Name: Gail L. Winokur